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APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,274	10/17/2001	Ralph Kafesjian	ECV-5627	6375
7590	02/08/2005		EXAMINER	
Edwards Lifesciences LLC Law Dept. One Edwards Way Irvine, CA 92614			JASTRZAB, KRISANNE MARIE	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/981,274	KAFESJIAN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Krisanne Jastrzab	1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-44 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 5/7/02, 2/6/03.

- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

Claims 13 and 14 are objected to because of the following informalities: both claims have grammatical errors. The term "is" following "fluorocarbons" and "alkanes" respectively, should properly be --are--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 15-16, 25-30 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 3, this claim is found to be vague and indefinite because it includes an improperly recited Markush group. The phraseology must be "selected from the group consisting of" for the grouping to be proper. Correction is required.

With respect to claim 15, the references in this claim to "said critical" and "near critical" lack proper antecedent basis because the independent claim recites only supercritical. Correction is required.

With respect to claims 16 and 25-30, "said animal matter" lacks proper antecedent basis.

With respect to claim 44, this claim is found to be vague and indefinite because it is unclear as to how "nucleic acids", "lipids" or "polysaccharides" can be considered to constitute "infectious agents". Clarification is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fages et al., U.S. patent No. 5,723,012 in view of Mills et al., U.S. patent No. 6,652,818 B1 and Kamarei U.S. patent No. 4,749,522.

Fages et al., substantially teach the invention as claimed, however, they are silent as to the specific application to soft tissue. Fages et al., teach treating tissue for implantation with a supercritical fluid such as carbon dioxide wherein the treatment has an antiviral effect on the tissue. The treatment is generally achieved with a flow contact such that 100 to 500 grams of the supercritical fluid is supplied per gram of tissue. Pressures and temperatures applied, are the same as those claimed in the instant claims. Fages et al., further teach that supercritical treatment also acts to remove other agents including proteins and nucleic acids from the tissue, and particularly teach the efficacy in removing viruses such as the HIV virus. The tissue can also be contacted with an ethanol. See column 1, line 65 through column 2, line 2, see also column 2, lines 45-51 and lines 63-68, column 3, lines 25-35, and lines 60-65, and column 4, lines 23-35.

Both Mills et al., and Kamarei teaches that it is known and expected to treat any type of implantable tissue equivalently, namely both bone and soft tissue. See column 7, line 59 through column 8, line 8 and column 8, lines 38-45, and column 12, lines 5-10 of Mills et al., and column 6, lines 25-55. Kamarei further teaches the known and expected inclusion of modifiers and entrainers in a supercritical fluid for tissue treatment, those including water, alcohols and acetones. Kamarei also teaches the efficacy of other supercritical fluids including chlorodifluoromethane and

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trifluoromethane with extraction of all of lipids, proteins, viruses, and nucleic acids, thereby achieving biological purification. See Table 7, column 7, line 60 through column 8, line 31, as well as column 8, lines 35-38 and 60-65.

It would have been obvious to one of ordinary skill in the art to apply the process of Fages to mammalian soft -tissue to achieve biological purification sufficient for the use of the tissue for subsequent implantation, because the equivalent treatment of different implant tissue types is well recognized and because the efficacy of supercritical extraction for all types of undesirable elements present in the tissue which could affect the success of subsequent implantation.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Krisanne Jasirzab  
Primary Examiner  
Art Unit 1744

February 7, 2005